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JUN 2 8 2012

510(k) Summary

June 28, 2012

K120996

Submitter

Company Name:	Paragon Vision Sciences, Inc.
Address:	945 East Impala Ave., Mesa, AZ 85204
Phone:	480-892-7602
Fax:	480-892-3226
Registration:	Owner Operator # 9024618
Registration:	Site Registration # 2020433

Official Correspondent

Name:	William E. Meyers, Ph.D.
Address:	% Paragon Vision Sciences, Inc.
Address:	945 East Impala Ave., Mesa, AZ 85204
Phone:	480-507-7606
Fax:	480-892-3226

Device Name

Trade & USAN Name:
FluoroPerm® 30 & Paragon Thin™ (paflufocon C) rigid gas permeable contact lenses
FluoroPerm® 60 & Paragon HDS® (paflufocon B) rigid gas permeable contact lenses
FluoroPerm® 92 (paflufocon A) rigid gas permeable contact lenses
FluoroPerm® 151 & Paragon HDS® 100 (paflufocon D) rigid gas permeable contact lenses

Classification & Ophthalmic Device Branch

Common Name:	Contact lens
Product Code:	86 HQD
Classification Name:	Rigid gas permeable contact lens for daily wear
Classification Panel:	Ophthalmic
Reference:	21 CFR 886.5916; rigid gas permeable Contact lens, Class II – daily wear contact lens

Device Name: FluoroPerm® 92 (paflufocon A) rigid gas permeable contact lenses
FluoroPerm® 60 (paflufocon B) rigid gas permeable contact lenses
Paragon HDS® (paflufocon B) rigid gas permeable contact lenses
FluoroPerm® 30 (paflufocon C) rigid gas permeable contact lenses
Paragon Thin™ (paflufocon C) rigid gas permeable contact lenses
FluoroPerm® 151 (paflufocon D) rigid gas permeable contact lenses
Paragon HDS® 100 (paflufocon D) rigid gas permeable contact lenses

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Indications for Use:

FluoroPerm® 92

FluoroPerm® 92 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm® 92 rigid gas permeable bifocal or toric contact lenses are indicated for daily wear only.

FluoroPerm® 92 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 92 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 92 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 92 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

FluoroPerm® 60

FluoroPerm® 60 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm® 60 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm® 60 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 60 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 60 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 60 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Paragon HDS®

Paragon HDS® rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as

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recommended by the eye care practitioner. Paragon HDS® rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

Paragon HDS® rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. Paragon HDS® toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon HDS® contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

FluoroPerm® 30

FluoroPerm® 30 rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm® 30 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 30 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 30 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 30 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Paragon Thin™

Paragon Thin™ rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

Paragon Thin™ rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. Paragon Thin™ toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon Thin™ bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

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In daily wear use only, Paragon Thin™ contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

FluoroPerm® 151

FluoroPerm® 151 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm® 151 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm® 151 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 151 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 151 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 151 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Paragon HDS® 100

Paragon HDS® 100 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. Paragon HDS® 100 rigid gas permeable bifocal or toric contact lenses are indicated for daily wear only.

Paragon HDS® 100 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. Paragon HDS® 100 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® 100 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon HDS® 100 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Predicate Device Classification Name: rigid gas permeable contact lenses (hydrophobic)

Proprietary Name:

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Boston XO (hexafocon A)	K053124	Date: Jan. 30, 2006
Boston EO (enflufocon B)	K053124	Date: Jan. 30, 2006
Boston ES (enflufocon A)	K053124	Date: Jan. 30, 2006
Boston XO2 (hexafocon B)	K071266	Date: Aug. 15, 2007
FluoroPerm® 92 (paflufocon A)	K070637	Date: May 1, 2007
FluoroPerm® 60 & Paragon HDS® (paflufocon B)	K070637	Date: May 1, 2007
FluoroPerm® 30 & Paragon Thin™ (paflufocon C)	K070637	Date: May 1, 2007
FluoroPerm® 151 & Paragon HDS® 100 (paflufocon D)	K070637	Date: May 1, 2007

Device Description:

FluoroPerm® 92, FluoroPerm® 60, Paragon HDS®, FluoroPerm® 30, Paragon Thin™, and FluoroPerm® 151, and Paragon HDS® 100 lenses are available as lathe cut rigid gas permeable contact lenses for daily wear only. The lenses are manufactured from these FDA approved contact lens materials; paflufocon A (FluoroPerm® 92), paflufocon B (FluoroPerm® 60, Paragon HDS®), paflufocon C (FluoroPerm® 30, Paragon Thin™), and paflufocon D (FluoroPerm® 151, Paragon HDS® 100). These materials are thermoset copolymers derived from fluorosilicone acrylate monomers.

The lenses may be tinted to offer a handling aid for locating the lens. The lenses may be available with an ultraviolet absorber (not in all colors and materials).

The lens designs have a posterior surface consisting of a base curve and a series of up to four annular spherical or aspheric curves peripheral to the base curve.

FluoroPerm® 92, FluoroPerm® 60, FluoroPerm® 151, Paragon HDS®, and Paragon HDS® 100 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm® 92, FluoroPerm® 60, FluoroPerm® 151, Paragon HDS®, and Paragon HDS® 100 rigid gas permeable bifocal or toric contact lenses are indicated for daily wear only.

FluoroPerm® 30 and Paragon Thin™ rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

The contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

The safety and effectiveness of paflufocon A (FluoroPerm® 92), paflufocon B (FluoroPerm® 60 and Paragon HDS®), paflufocon C (FluoroPerm® 30 and Paragon Thin™) and paflufocon D (FluoroPerm® 151 and Paragon HDS® 100) materials as rigid gas permeable contact lenses have been demonstrated in PMA P870024 and several of its supplements.

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The properties of Paflufocon A (FluoroPerm® 92), paflufocon B (FluoroPerm® 60 and Paragon HDS®), paflufocon C (FluoroPerm® 30 and Paragon Thin™) and paflufocon D (FluoroPerm® 151 and Paragon HDS® 100) materials are unchanged, a wide range of larger diameter lenses are now in the market made with lens materials of similar properties such as the predicate materials (Boston XO2 (K071266), Boston XO, Boston EO, and Boston ES (K053124)). Boston XO2 (K071266) has a chord diameter scleral range up to 25.0 mm whereas the FluoroPerm and HDS Families' chord diameters were approved years ago with a chord diameter up to 16.0 mm which limits the use of the scleral lens range. The FluoroPerm and HDS Families' expanded the chord diameter range to include scleral lenses up to 25.0 mm, comparable to the predicate Boston XO2. Our labeling includes fitting instructions appropriate for such larger diameter lenses within the scleral (15.0-25.0 mm) range.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Paragon Vision Sciences, Inc.
c/o William E. Meyers, Ph.D.
Vice President of Science & Technology
947 East Impala Avenue
Mesa, AZ 85204

JUN 28 2012

Re: K120996
Trade/Device Name: FluoroPerm® 30 and Paragon Thin™ (paflufocon C); FluoroPerm® 60 and Paragon HDS® (paflufocon B); FluoroPerm® 92 (paflufocon A); and FluoroPerm® 151 and Paragon HDS® 100 (paflufocon D) Rigid Gas Permeable (RGP) Contact Lenses for Daily Wear
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lens
Regulatory Class: Class II
Product Code: HQD
Dated: March 22, 2012
Received: April 2, 2012

Dear Dr. Meyers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K120996:

Device Name: FluoroPerm® 92 (paflufocon A) rigid gas permeable contact lenses

Indications for Use:

FluoroPerm® 92

FluoroPerm® 92 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm® 92 rigid gas permeable bifocal or toric contact lenses are indicated for daily wear only.

FluoroPerm® 92 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 92 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 92 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 92 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Prescription Use ____X____ OR Over-The-Counter Use _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Hampton for Krawczyk

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120996

Indications for Use

510(k) Number K120996:

Device Name: FluoroPerm® 60 (paflufocon B) rigid gas permeable contact lenses

Indications for Use:

FluoroPerm® 60

FluoroPerm® 60 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm® 60 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm® 60 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 60 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 60 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 60 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Prescription Use ___X___ OR Over-The-Counter Use _____

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510(k) Number K120996

K120996

Indications for Use

510(k) Number K120996:

Device Name: Paragon HDS® (paflufocon B) rigid gas permeable contact lenses Paragon

Indications for Use:

Paragon HDS®

Paragon HDS® rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. Paragon HDS® rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

Paragon HDS® rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. Paragon HDS® toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon HDS® contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Prescription Use ___X___ OR Over-The-Counter Use _____

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510(k) Number K120996

K120996

Indications for Use

510(k) Number K120996:

Device Name: FluoroPerm® 30 (paflufocon C) rigid gas permeable contact lenses

Indications for Use:

FluoroPerm® 30

FluoroPerm® 30 rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

FluoroPerm® 30 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 30 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 30 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 30 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Prescription Use ____X____ OR Over-The-Counter Use _____

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510(k) Number K120996

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Indications for Use

510(k) Number K120996:

Device Name: Paragon Thin™ (paflufocon C) rigid gas permeable contact lenses

Indications for Use:

Paragon Thin™

Paragon Thin™ rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

Paragon Thin™ rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. Paragon Thin™ toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon Thin™ bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon Thin™ contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Prescription Use __X__ OR Over-The-Counter Use _____

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Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K120996

Indications for Use

510(k) Number K120996:

Device Name: FluoroPerm® 151 (paflufocon D) rigid gas permeable contact lenses

Indications for Use:

FluoroPerm® 151

FluoroPerm® 151 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. FluoroPerm® 151 rigid gas permeable bifocal, or toric contact lenses are indicated for daily wear only.

FluoroPerm® 151 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. FluoroPerm® 151 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. FluoroPerm® 151 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, FluoroPerm® 151 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Prescription Use ____X____ OR Over-The-Counter Use _____

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Nose and Throat Devices

510(k) Number K120996

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Indications for Use

510(k) Number K120996:

Device Name: Paragon HDS® 100 (paflufocon D) rigid gas permeable contact lenses

Indications for Use:

Paragon HDS® 100

Paragon HDS® 100 rigid gas permeable spherical or aspheric contact lenses are indicated for daily wear and extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. Paragon HDS® 100 rigid gas permeable bifocal or toric contact lenses are indicated for daily wear only.
Paragon HDS® 100 rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. Paragon HDS® 100 toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters. Paragon HDS® 100 bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

In daily wear use only, Paragon HDS® 100 contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery in otherwise non-diseased eyes.

Prescription Use X OR Over-The-Counter Use _____

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